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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Propofol Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for expanding the indications to include the use of propofol in cats.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed supplemental NADA 141–070 that provides for intravenous use in cats of Rapinovet Anesthetic Injection (each milliliter contains 10 milligrams of propofol). The product was previously approved for use in dogs. The drug is used as a single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to affect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics. The drug is limited to use by or on the order of a licensed veterinarian. The supplemental NADA is approved as of January 14, 1999, and the regulations are amended in 21 CFR 522.2005 by revising paragraph (b) and by adding paragraph (c)(2) to reflect the approval. The basis of approval is provided in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for a 3-year period of marketing exclusivity beginning January 14, 1999, because the supplement application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species (cats) for which the supplemental application was approved.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.2005 is amended by revising paragraph (b) and by adding paragraph (c)(2) to read as follows:

§ 522.2005 Propofol injection.

* * * * *

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraphs (c)(1) and (c)(2) of this section. See No. 000074 in § 510.600(c) of this chapter for use as in paragraph (c)(1) of this section.

(c) * * *

(2) *Cats.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to effect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 8.0 to 13.2 milligrams per kilogram (3.6 to 6.0 milligrams per pound). For the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 4.4 milligrams per kilogram (0.5 to 2.0 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding cats have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 2/23/99
February 23, 1999

Stephen F. Sundlof
Director
Center for Veterinary
Medicine

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